

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
22 August 2002 (22.08.2002)

PCT

(10) International Publication Number
WO 02/064203 A1

(51) International Patent Classification: A61M 39/06

(21) International Application Number: PCT/US01/28437

(22) International Filing Date:
13 September 2001 (13.09.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/782,764 13 February 2001 (13.02.2001) US

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(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 02/064203 A1

(54) Title: HEMOSTASIS VALVE

(57) Abstract: A hemostasis valve which provides a fluid tight seal at all times to prevent back-bleeding, and offers relatively low friction when devices are inserted therein. The hemostasis valve may either be an integral part of a tubular device (e.g., sheath, catheter, or the like) or releasable from the tubular device (e.g., Y-adapter or the like). In one embodiment, the hemostasis valve is biased to a closed position in response to distal pressure to prevent back-bleeding. The hemostasis valve is also biased to an open position in response to proximal force or pressure to reduce friction when devices are inserted therein. For example, the hemostasis valve may comprise a plurality of leaflets or flaps. In another embodiment, the hemostasis valve is longitudinally actuated between an open position to reduce friction during device insertion and a closed position to prevent back-bleeding when no devices are inserted therein.

HEMOSTASIS VALVE

Field of the Invention

The present invention generally relates to devices incorporating hemostasis valves. More specifically, the present invention relates to hemostasis valves for use
5 with vascular introducer sheaths, catheters, Y-adapters and the like.

Background of the Invention

Vascular introducer sheaths are well known components of vascular access systems which are used in a wide variety of diagnostic and therapeutic vascular procedures, such as angiography, angioplasty and embolization procedures. Vascular
10 access systems typically include an introducer sheath and a dilator. The introducer sheath usually includes a hemostasis valve which inhibits blood loss as guide wires, catheters and the like are introduced, passed through and manipulated in the sheath.

An example of a conventional vascular access system 10 is illustrated in Figure 1. The vascular access system 10 includes two primary components, namely
15 an introducer sheath 12 and a dilator 14. The introducer sheath 12 includes an elongate shaft 16 and a hemostasis valve assembly 18. A flush tube subassembly 20 may be connected to a side port 22 of the hemostasis assembly 18. Although not clearly visible, the hemostasis valve assembly 18 includes a hub, a cap and a gasket 30 (shown in Figures 2A and 2B) disposed therebetween.

20 The gasket 30 of the hemostasis valve assembly 18 forms a fluid seal about devices inserted therein to inhibit back-bleeding. The gasket 30 may comprise a disc of flexible polymeric material having a slit 32 extending therethrough as shown in Figure 2A or a hole 34 as shown in Figure 2B. The slit 32 is sufficiently flexible and the hole 34 is sufficiently sized to form a seal about devices inserted therein. The slit
25 32 is normally closed such that a hemostatic seal is formed with or without devices inserted therein. By contrast, the hole 34 is normally open such that a hemostatic seal is formed only with a device inserted therein.

An advantage of the slit 32 design is that back-bleeding is prevented at all times – prior to, during and subsequent to device insertion. A disadvantage of the slit
30 32 design is that a significant amount of friction may be encountered when sliding devices therethrough. An advantage of the hole 34 design is that relatively little friction is encountered when sliding devices therethrough. A disadvantage of the hole 34 design is that back-bleeding may occur when no device is inserted therein (i.e., prior to and subsequent to device insertion). Accordingly, there is a need for a

hemostasis valve which provides a fluid tight seal at all times to prevent back-bleeding, and offers relatively low friction when devices are inserted therein.

Summary of the Invention

To address this need, the present invention provides an improved hemostasis valve for use with an intravascular device such as an introducer sheath, a catheter or the like. In all embodiments, the hemostasis valve may either be an integral part of the device, or releasable from the device as in a Y-adapter, a manifold or the like.

In one embodiment, the hemostasis valve is normally closed and is biased to a closed position in response to distal pressure to prevent back-bleeding. The hemostasis valve is also biased to an open position in response to proximal force or pressure to reduce friction when devices are inserted therein. For example, the hemostasis valve may comprise a plurality of flaps or leaflets, such as a bileaflet or trileaflet design. Preferably, the leaflets are cuspidate, such as a bicuspid or tricuspid design. Also preferably, the thickness of the leaflets is substantially less than the radial dimension thereof such that the leaflets readily deflect and conform. As an alternative, another hemostasis valve (e.g., a close-fit seal) may be utilized to ensure a fluid tight seal about devices inserted therein.

In another embodiment, the hemostasis valve is longitudinally actuated between an open position to reduce friction during device insertion and a closed position to prevent back-bleeding when no devices are inserted therein. The hemostasis valve may include a circular or helical pleat which changes in radial dimension upon longitudinal actuation. For example, the hemostasis valve may be bellows-shaped. The hemostasis valve may also include a radial compression member that toggles when the valve is closed to ensure a fluid tight seal.

Brief Description of the Drawings

Figure 1 is a plan view of a conventional vascular access system including an introducer sheath and a dilator;

Figure 2A is a plan view of a conventional slit-type gasket used in the hemostasis valve subassembly of the introducer sheath illustrated in Figure 1;

Figure 2B is a plan view of a hole-type gasket used in the hemostasis valve subassembly of the introducer sheath illustrated in Figure 1;

Figure 3 is a plan view of an introducer sheath in accordance with an embodiment of the present invention;

Figure 4A is a cross-sectional view taken along line 4-4 in Figure 3, showing the brake mechanism in the disengaged position;

Figure 4B is a cross-sectional view taken along line 4-4 in Figure 3 showing the brake mechanism in the engaged position;

5 Figure 5A is a longitudinal sectional view taken along line 5-5 in Figure 3, showing an active and a passive hemostasis valve in accordance with an embodiment of the present invention;

Figure 5B is a longitudinal sectional view taken along line 5-5 in Figure 3, showing a tubular catheter extending through the active and passive hemostasis valves
10 illustrated in Figure 5A;

Figure 6A is a cross-sectional view taken along line 6-6 in Figure 5A, showing a bileaflet valve design in accordance with an embodiment of the present invention;

Figure 6B is a cross-sectional view taken along line 6-6 in Figure 5A, showing a trileaflet valve design in accordance with an embodiment of the present invention;

15 Figure 7 is a plan view of an introducer sheath in accordance with another embodiment of the present invention;

Figure 8A is a longitudinal sectional view taken along line 8-8 in Figure 7, showing a hemostasis valve in the closed position; and

Figure 8B is a longitudinal sectional view taken along line 8-8 in Figure 7, showing the hemostasis valve in the open position with a guide wire extending
20 therethrough.

Detailed Description of the Invention

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same.
25 The drawings, which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Refer now to Figure 3 which illustrates a side view of an introducer sheath 100 in accordance with an embodiment of the present invention. The introducer sheath 100 includes an elongate shaft 110 having a proximal portion 112, a distal portion 114
30 and a lumen 116 extending therethrough. A hub assembly 120 is connected to the proximal portion 112 of the shaft 110. A tapered distal tip is connected to the distal portion 114 of the elongate shaft 110 to facilitate smooth insertion into the vascular system. The introducer sheath 100, with the exception of the hub assembly 120 and hemostasis valves 130/140 (discussed hereinafter), may have conventional

dimensions and may be formed of conventional materials known in the art. For example, the shaft 110 may have a size ranging from 4F to 14F and a length ranging from 10 cm to 25 cm, and may comprise a tubular polymeric extrusion.

The hub assembly 120 includes a housing or body portion 128 which contains
5 a brake mechanism 150 (discussed hereinafter). The housing or body portion 128 includes a proximal flared portion 122 and a distal strain relief 124. The flared proximal portion 122 includes a proximal opening (not visible) leading to a lumen 126 extending through the hub assembly 120. The strain relief 124 facilitates a kink-resistant connection to the proximal portion 112 of the shaft 110. With this
10 arrangement, other intravascular devices (e.g., tubular catheters 40, guide wires 50, etc) may be inserted into the opening of the flared proximal portion 122, through the lumen 126 of the hub 120, through the lumen 116 of the shaft 110, and into the patient's vascular system. A suture ring 123 may be connected to the housing 128 to secure the introducer sheath 110 to the patient.

15 The brake mechanism 150 is slidably disposed in the housing 128 of the hub assembly 120 between a disengaged position as shown in Figure 4A and an engaged position as illustrated in Figure 4B. In the engaged position, the brake mechanism 150 limits relative longitudinal movement between the introducer sheath 100 and devices inserted therein. Those skilled in the art will recognize that many alternative
20 mechanisms may be used in place of brake mechanism 150 to perform the same or similar function.

The brake mechanism 150 includes opposing buttons 152 which are slidably disposed in similarly shaped openings (not visible) defined in the housing 128. The brake mechanism 150 also includes a collar 154 having an inside diameter
25 approximately equal to the inside diameter of the hub lumen 126, which is approximately equal to the inside diameter of the shaft lumen 116. When the brake mechanism is in the disengaged position as illustrated in Figure 4A, the lumen of the collar 154 is in alignment with the hub lumen 126 to define a through passage having a nominal diameter D_1 . When the brake mechanism 150 is in the engaged position as
30 illustrated in Figure 5B, the lumen of the collar 154 is in misalignment relative to the hub lumen 126 to define a through passage having a reduced diameter D_2 .

The brake mechanism 150 may be engaged and disengaged by applying a manual force to one of the push buttons 152 as shown, for example, by arrow 156. By engaging the brake mechanism 150, the collar 154 frictionally engages devices

extending therethrough by virtue of the reduced diameter D_2 and the misalignment with the hub lumen 126. The degree of frictional engagement may be modified, for example, by varying the displacement of the collar 154, and/or by varying the coefficient of friction of the collar 154. Although not shown, the brake mechanism 5 150 may incorporate a biasing member such as a spring to preferentially bias the brake mechanism 150 to either the engaged position or the disengaged position.

The introducer sheath 100 includes an active hemostasis valve 130 and a passive hemostasis valve 140. The active hemostasis valve 130 and the passive hemostasis valve 140 are adapted to seal about a wide variety of intravascular devices 10 such as a catheter 40 or a guide wire 50. The hemostasis valves 130/140 may be incorporated into a wide variety of intravascular tubular devices such as an introducer sheath, a catheter or the like. The hemostasis valves 130/140 may be incorporated into any portion of the tubular device (e.g., hub or shaft), at a common position or at different positions. In addition, the hemostasis valves 130/140 may be an integral part 15 of the tubular device or releasably connected thereto as with a Y-adaptor, a manifold, or the like. For purposes of illustration only, the hemostasis valves 130/140 are shown in Figures 5A and 5B to be an integral part of the distal portion 114 of the elongate shaft 110 of the introducer sheath 100, which offers certain advantages.

The active hemostasis valve 130 is normally closed and is biased to a closed 20 position as shown in Figure 5A in response to distal pressure to minimize back-bleeding when no device extends therethrough. The active hemostasis valve 130 is also preferably biased to an open position in response to proximal force or pressure when devices are inserted therein to reduce friction therebetween.

The active hemostasis valve 130 may comprise a plurality of leaflets or flaps 25 132. For example, the active hemostasis valve 130 may include two leaflets (bileaflet design) or three leaflets (trileaflet design). Preferably, the leaflets 132 are cuspidate and thereby form a cusp 134. With a bileaflet design as seen in Figure 6A, the leaflets 132 define a bicuspid interface 134A. With a trileaflet design as shown in Figure 6B, the leaflets 132 form a tricuspid interface 134B.

30 In either embodiment, the leaflets 132 preferably have a thickness that is substantially less than the radial dimension thereof such that the leaflets are extremely flexible and readily deflect and conform to devices extending therethrough. For example, the thickness of the leaflets 132 may be 1% - 10% of the radial dimension

thereof. The leaflets 132 may be formed of a relatively flexible material such as an elastomeric polymeric material (e.g., polyisoprene rubber).

The passive hemostasis valve 140 is normally open to allow devices to freely pass therethrough. The passive hemostasis valve 140 provides a close-fit, relatively low friction, fluid tight seal about devices inserted therein. The passive hemostasis valve 140 may comprise a flexible polymeric O-ring 142 having an inside diameter which is approximately equal to the outside diameter of the intravascular device (e.g., catheter 40) extending therethrough. The inside diameter of the O-ring 142 may be slightly less than the outside diameter of the catheter 40 to create an interference fit which provides a relatively high pressure seal therebetween. Alternatively, the O-ring 142 may have an inside diameter that is slightly greater than the outside diameter of the catheter 40 to define a gap fit which provides a relatively low friction seal therebetween. The passive hemostasis valve 140 ensures a fluid seal about devices inserted therethrough to the extent that the active hemostasis valve 130 does not provide a sufficiently tight seal.

Refer now to Figure 7 which illustrates a plan view of introducer sheath 200 in accordance with another embodiment of the present invention. The introducer sheath 200 includes an elongate shaft 210 having a proximal portion 212, a distal portion 214 and a lumen 216 extending therethrough. A hub assembly 220 is connected to the proximal portion 212 of the elongate shaft 210. The distal portion 214 of the elongate shaft 210 includes a tapered tip to facilitate insertion into the patient's vascular system. The introducer sheath 200, with the exception of the hub assembly 220, may have conventional dimensions and may be formed of conventional materials known in the art. For example, the shaft 210 may have a size ranging from 4F to 14F and a length ranging from 10 cm to 25 cm, and may comprise a tubular polymeric extrusion.

Hub assembly 220 includes a tubular housing 222 having a proximal end and a distal end. A strain relief 226 is connected to the distal end of the housing 222 by way of connection member 224. The strain relief 226 facilitates a kink-resistant connection to the proximal portion 212 of the shaft 210. The hub assembly 220 further includes a cap 228 which is slidably disposed about the housing 222. The cap 228 includes a proximal opening 229.

The hub assembly 220 further includes an active hemostasis valve 250 having a proximal end and a distal end. The proximal end of the active hemostasis valve 250 is connected the proximal end of the cap 228. The distal end of the active hemostasis

valve 250 is connected the distal end of the housing 222. The active hemostasis valve 250 includes a passageway 255 which may be selectively closed as illustrated in Figure 8A and selectively opened as illustrated in Figure 8B. A biasing member 230 such as a helical spring may be disposed between the cap 228 and the housing 222 to preferentially bias the hemostasis valve 250 to the closed position or the open position. A lock mechanism (not shown) such as a push-button pin or quarter-turn stop may be used to activate or deactivate the biasing member 230.

The active hemostasis valve 250 includes a plurality of tubular pleats 253 defined by a plurality of wall members 252 connected at circular or helical hinge points 254. For example, the plurality of pleats 253 may resemble a bellows. The active seal 250 may be longitudinally displaced to selectively open and close the passage 255 extending therethrough. The active hemostasis valve 250 may be longitudinally displaced by moving the cap 228 relative to the housing 222. Thus, the passage 255 may be closed by moving the cap 228 in a distal direction relative to the housing 222 as illustrated in Figure 8A. Similarly, the passage 255 may be opened by displacing the cap 228 in a proximal direction relative to the housing 222 as illustrated in Figure 8B. In the closed position, the active hemostasis valve 250 prevents back-bleeding through the lumen 216. In the open position, the active hemostasis valve 250 permits insertion of a catheter 40 or a guide wire 50 through the passage 255.

The hemostasis valve 250 may include a radial compression member 256 having an outer perimeter connected to the housing 222 and an inner perimeter connected to the outside surface of a pleat 253 adjacent an inside hinge point 254. The radial compression member 256 toggles to a closed position as illustrated in Figure 8A to ensure a fluid tight seal and thereby prevent back-bleeding. The radial compression member 256 is radially rigid in the closed position as shown in Figure 8A and radially flexible in the open position as illustrated in Figure 8B. The radial compression member 256 may comprise, for example, a thin disk having a central opening disposed about an inside hinge point 254.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.

What is claimed is:

1. An intravascular device adapted to accommodate another intravascular device therein, the intravascular device comprising:

a shaft having a proximal portion, a distal portion and a lumen extending therethrough; and

a first hemostasis valve connected to the shaft, the first hemostasis valve being biased to an open position in response to proximal pressure and biased to a closed position in response to distal pressure.

2. An intravascular device as in claim 1, wherein the first hemostasis valve is normally closed.

3. An intravascular device as in claim 1, wherein the first hemostasis valve is releasably connected to the shaft.

4. An intravascular device as in claim 1, wherein the first hemostasis valve comprises a plurality of leaflets.

5. An intravascular device as in claim 3, wherein the leaflets are cuspidate.

6. An intravascular device as in claim 5, wherein the leaflets have a radial dimension and a thickness, and wherein the thickness is substantially less than the radial dimension such that the leaflets readily deflect.

7. An intravascular device as in claim 1, further comprising a second hemostasis valve connected to the shaft, the second hemostasis valve being normally open.

8. An intravascular device as in claim 7, wherein the second hemostasis valve is passive.

9. An intravascular device as in claim 8, wherein the first hemostasis valve is connected to a distal portion of the shaft.

10. An intravascular device adapted to accommodate another intravascular device therein, the intravascular device comprising:

a shaft having a proximal portion, a distal portion and a lumen extending therethrough;

a first hemostasis valve connected to the shaft, the first hemostasis valve being active; and

a second hemostasis valve connected to the shaft, the second hemostasis valve being passive.

11. An intravascular device as in claim 10, wherein the first hemostasis valve is biased to an open position in response to proximal pressure and is biased to a closed position in response to distal pressure.

12. An intravascular device as in claim 11, wherein the first hemostasis valve comprises a plurality of leaflets.

13. An intravascular device as in claim 12, wherein the first hemostasis valve is normally closed.

14. An intravascular device as in claim 13, wherein the second hemostasis valve is normally open.

15. An intravascular device adapted to accommodate another intravascular device therein, the intravascular device comprising:

a shaft having a proximal portion, a distal portion and a lumen extending therethrough;

a hemostasis valve connected to the shaft, the hemostasis valve being longitudinally actuatable between an open position and a closed position.

16. An intravascular device as in claim 15, wherein the hemostasis valve is releasably connected to the shaft.

17. An intravascular device as in claim 15, wherein the hemostasis valve includes a pleat which changes in radial dimension upon longitudinal actuation.

18. An intravascular device as in claim 17, wherein the hemostasis valve is bellows-shaped.

19. An intravascular device as in claim 17, wherein the hemostasis valve includes a toggled compression member.

20. A method of using a hemostasis valve, comprising the steps of:
providing an intravascular device adapted to accommodate another intravascular device therein, the intravascular device including a shaft having a proximal portion, a distal portion and a lumen extending therethrough;
providing a hemostasis valve connected to the shaft; and
longitudinally actuating the hemostasis valve between an open position and a closed position.

21. A method of using a hemostasis valve as in claim 20, wherein the hemostasis valve is releasably connected to the shaft, further comprising the step of connecting the hemostasis valve to the shaft.

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Fig. 1

PRIOR ART

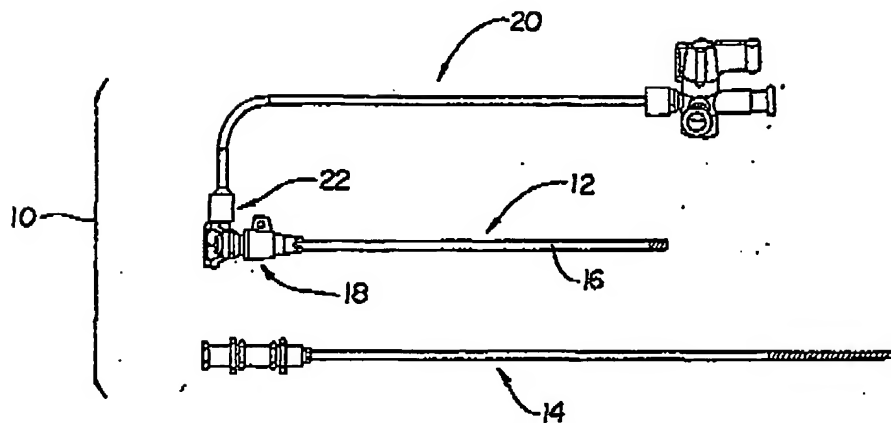


Fig. 2A

PRIOR ART

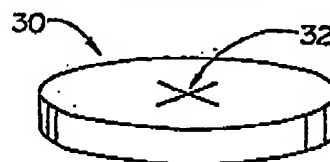
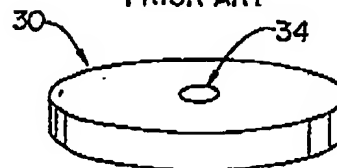


Fig. 2B

PRIOR ART



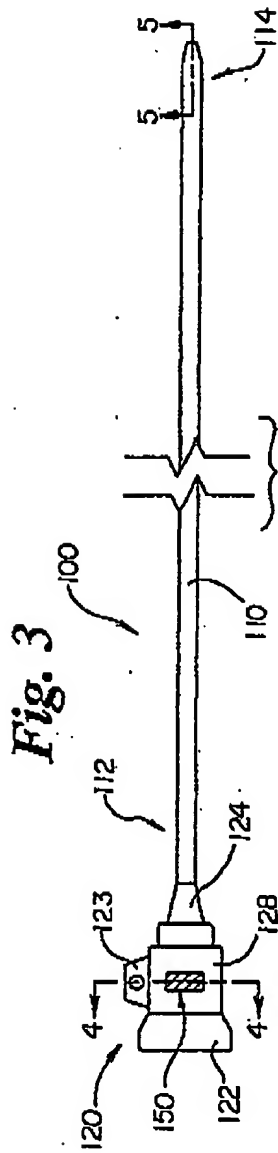


Fig. 5A

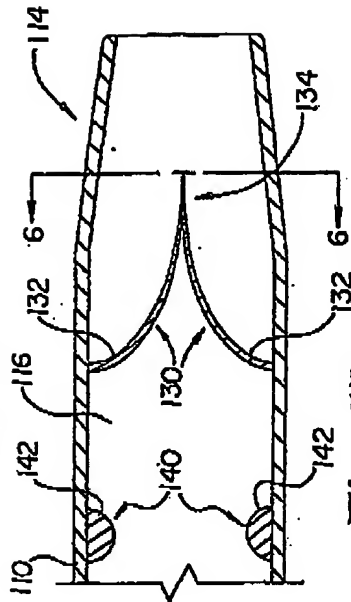


Fig. 5B

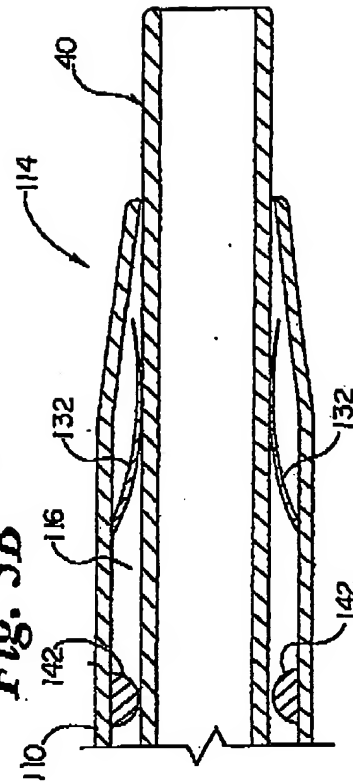


Fig. 4A

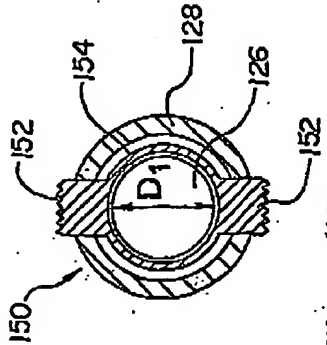
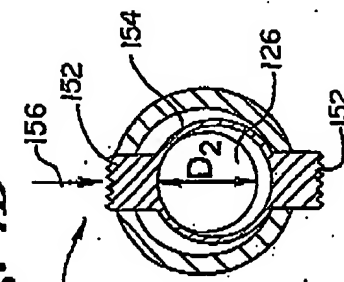


Fig. 4B



3/3

Fig. 6A

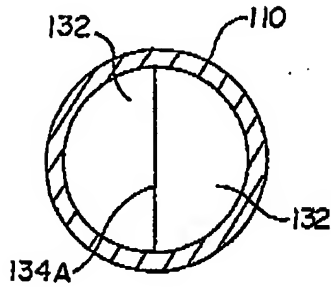


Fig. 6B

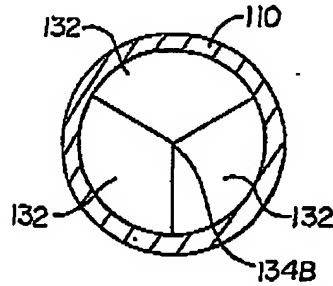


Fig. 7

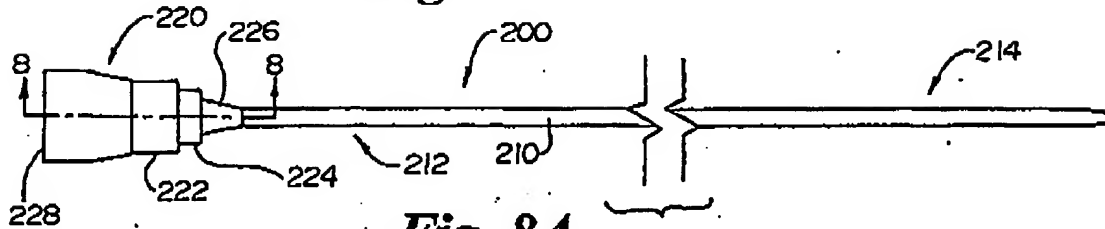


Fig. 8A

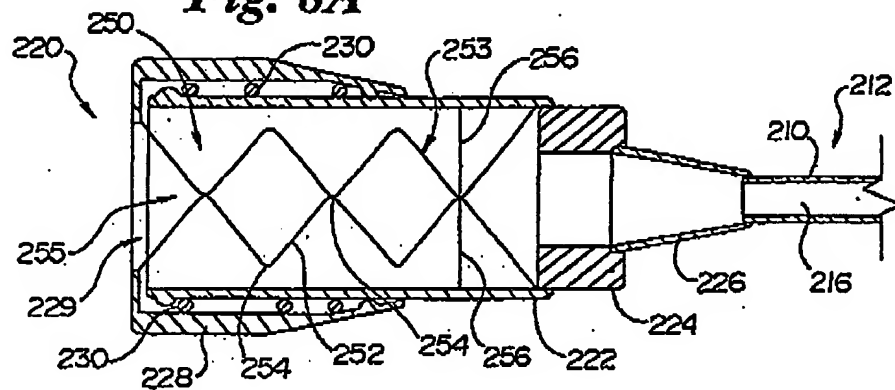
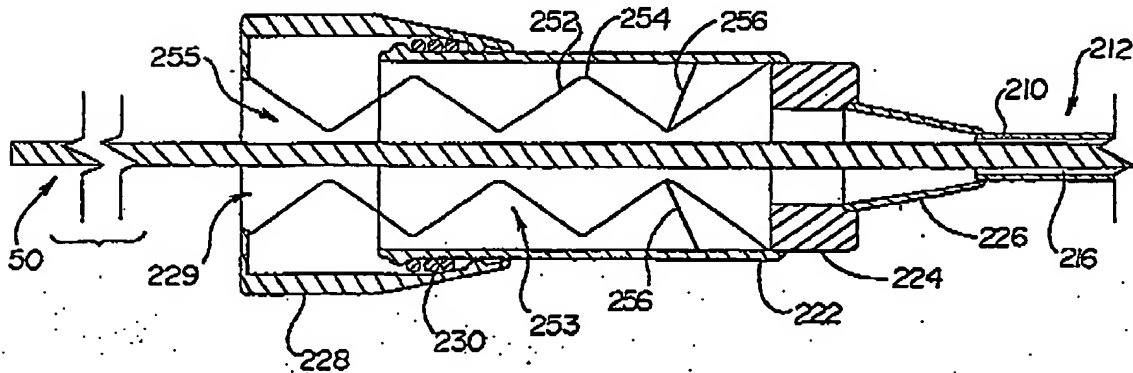


Fig. 8B



A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61M39/06		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 269 763 A (STELLO GERARDUS M ET AL) 14 December 1993 (1993-12-14) column 2, line 63 -column 4, line 42; figures 1-6	1-6
X	US 4 960 412 A (FINK E DAVID) 2 October 1990 (1990-10-02) column 3, line 41 -column 5, line 40; figures 1-5	1-4,7,8, 10-14
X	US 5 300 033 A (MILLER GARY H) 5 April 1994 (1994-04-05) abstract; figures 1,4,6	10-14
X	US 5 752 970 A (YOON INBAE) 19 May 1998 (1998-05-19) abstract; figures 8,9	1,2,4
A		9
<input type="checkbox"/> Further documents are listed in the continuation of box C. <input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 5 March 2002		Date of mailing of the international search report 05.06.2002
Name and mailing address of the ISA European Patent Office, P.O. Box 5818 Patentplan 2 NL - 2280 HV Rijswijk Tel: (+31-70) 340-2040, Tx. 81 851 epo nl, Fax: (+31-70) 340-8018		Authorized officer SCHOENLEBEN J.

INTERNATIONAL SEARCH REPORT

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20, 21
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-9, 10-14

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1998)

International Application No. PCT/US 01/28437

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-9, 10-14

An intravascular device comprising an active hemostasis valve

2. Claims: 15-19

An intravascular device comprising a longitudinally actuatable hemostasis valve

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5269763	A	14-12-1993	NONE	
US 4960412	A	02-10-1998	NONE	
US 5300033	A	05-04-1994	AT 195661 T	15-09-2000
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